



**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**In re Application of:**

Berry et al.

**Serial No.:** 09/497,422

**Filed:** February 3, 2000

**For:** STABLE NON-AQUEOUS SINGLE  
PHASE VISCOUS VEHICLES AND  
FORMULATIONS UTILIZING SUCH  
VEHICLES

**Confirmation No.:** 7482

**Examiner:** B. Fubara

**Group Art Unit:** 1618

**Attorney Docket No.:** 3139-6169US  
(ARC 2914 US R1)

**Notice of Allowance Mailed:**

November 21, 2006

**NOTICE OF EXPRESS MAILING**

Express Mail Mailing Label Number: EV962337536US

Date of Deposit with USPS: February 21, 2007

Person making Deposit: Di Sanders

**TRANSMITTAL LETTER**

Mail Stop Issue Fee  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Applicants submit herewith Part B - Fee(s) Transmittal for the above-captioned application and a check in the amount of \$1,400.00 in payment therefor.

Serial No. 09/497,422

Also enclosed are Amendment Pursuant to 37 C.F.R. § 1.312(a); Comments on Statement of Reasons for Allowance; and Fee Addressee for Receipt of PTO Notices Relating to Maintenance Fees.

Applicants understand that no additional fees are required. However, if the Office determines that any comparison fees or other additional fees are required, the Commissioner is authorized to charge any such fees to TraskBritt Deposit Account No. 20-1469. A copy of this Transmittal Letter is enclosed for deposit account charging purposes.

Respectfully submitted,



Edgar R. Cataxinos  
Registration No. 39,931  
Attorney for Applicants  
TRASKBRITT  
P.O. Box 2550  
Salt Lake City, Utah 84110-2550  
Telephone: 801-532-1922

Date: February 21, 2007

ERC/dlm:tp

Enclosures: Part B - Issue Fee Transmittal

Check No. 23494 in the amount of \$1,400.00

Copy of Transmittal Letter

Amendment Pursuant to 37 C.F.R. § 1.312(a) (12 pages) with attached

Replacement Sheet (1 sheet) and Annotated Sheet Showing Changes (1 sheet)

Comments on Statement of Reasons for Allowance (3 pages)

Fee Addressee for Receipt of PTO Notices Relating to Maintenance Fees (2 pages)

Document in ProLaw



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**COMMENTS ON STATEMENT OF REASONS FOR ALLOWANCE**

Mail Stop Issue Fee  
Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Sir:

This communication is filed in response to the Notice of Allowance mailed November 21, 2006 and sets forth Applicant's comments, pursuant to 37 C.F.R. §1.104(e), on the Examiner's Statement of Allowable Subject Matter accompanying the Notice of Allowance.

In the Notice of Allowance, the Examiner indicates:

Gyory (5,668,170) provided by applicant on Form 1449 filed 8/4/06, studies electrotransport effect of surfactants such as lauryl sulfate (column 12, line 64), polyethylene glycol monolaurate (column 12, lines 65 and 66), lauryl lactate (column 13, line 2), polysorbate column 13, line 4), dodecyl pyrrolidone (column

13, line 6) and decyl methyl sulfoxide (column 13, line 8). To study the electrotansport enhancing effects of the above surfactants, each surfactant was added to metoclopramide hydrochloride (Example 1) in aqueous solution. Polyvinyl pyrrolidone may be blended with the drug (column 10, lines 32, 33, 39 and 40) in the drug/agent reservoir. Table 1 looks at the effect of the individual surfactant on the flux of the metoclopramide. Gyory at column 14, line 54 through column 15, line 16 discusses that lauryl lactate, while reducing skin resistivity, does not enhance mass flux of metoclopramide (column 14, lines 63-65); that polysorbate-20 failed to have significant effect on either the electrotransport flux of metoclopramide or skin resistivity (column 14, line 66 through column 14 line 1). Thus, while it is clear that Gyory's composition is aqueous and differs from the non-aqueous single phase viscous composition of the instant claims, Gyory's findings does not encourage the use of either lauryl lactate or polysorbate as mass flux enhancers for the beneficial agent, metoclopramide. Gyory does not also show that a combination of surfactants such as lauryl lactate and polysorbate would enhance the mass flux of metoclopramide so that there would not be motivation to use a combination of lauryl lactate and polysorbate with metoclopramide to enhance the mass flux.

An obviousness type double patenting rejection would be made in the later filed co-pending application number 10/319,277 (filed 12/12/2002), while this application, which is an earlier filed application (filed 2/3/2000) is allowed to go to issue.

Therefore, the pending claims are allowable.

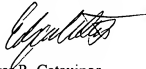
Applicants concur with the reasons as stated by the Examiner insofar as they comprise a summary, which is exemplary and not limiting. However, the scope of the claims is based on the actual language of the claims and equivalents thereof, and not on a paraphrase or summary of the claim language.

The Independent claims as allowed recite features and methodology in addition to, and in different language than, those described in the Statement of Allowable Subject Matter. Furthermore, the dependent claims recite elements in addition to those of the independent claims, which are also not reflected in the Statement of Allowable Subject Matter. Such additional elements, in combination with those of the independent claims from which each claim depends, provide additional reasons for patentability. Accordingly, the scope of the claims must be determined from the literal language of each as a whole, as well as all equivalents thereof.

Therefore, to the extent that the Examiner's reasons for allowance as stated are not relevant to, or wholly encompassing of, a particular claim, independent or dependent, Applicants

assume that (pursuant to 37 C.F.R. §1.104(e)) the Examiner has determined that the record of the prosecution as a whole of the application makes clear the reasons for allowing those claims. Further, it appears, pursuant to M.P.E.P. 1302.14, that the Examiner's Statements of Allowable Subject Matter are not intended to encompass all of the reasons for allowance.

Respectfully submitted,



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